REMARKS

Applicants gratefully acknowledge the rejoinder of claims such that claims 1-8, 11-12, 19, 21, 34 and 42-56, are under active consideration. Claims 13-16, 27, 29, 35 and 40 are pending but withdrawn by the Examiner. Applicants reserve all rights to pursue the subject matter of the withdrawn claims in another co-pending or subsequent application.

Objection to Specification and Claims

The specification, (and claims 3 and 4) are objected to as improperly using the trademark "ATCC".

In response, it is respectfully submitted that, as used in the specification and as explicitly stated in the specification at page 6, line 34, the term "ATCC" is not used as a trademark, but rather as an abbreviation of the depository, American Type Culture Collection. Such use is completely consistent with the use of this abbreviation by the American Type Culture Collection itself. Attention is directed to Exhibit 1, submitted herewith. Exhibit 1 is a "print out" from the website of the American Type Culture Collection indicating the contact information for that depository. As indicated in Exhibit 1, only a specific stylized version of the letters "ATCC" is used, respectively, as a registered trademark and a common law trademark by the depository. (See upper left hand portion of Exhibit 1).

On the contrary, a non-trademarked, non-stylized "ATCC" is used as abbreviation for the entity's name. See the remainder of Exhibit 1 where the abbreviation "ATCC" is used throughout without any indication of registered or common law trademark. It is the latter that is used in the present specification and claims as an abbreviation of the depository.

Accordingly, it is submitted that the objection to the specification and to the claims is avoided or in error and must be withdrawn.

Provisional Double Patenting Rejections

Claims 1-8, 11-12, 19, 21, 34 and 42-56 of this application are provisionally under Section 101 double patenting with claims 1, 3, 4, 6-10, 12, 19, 21, 27 and 33-56 of co-pending Application No.08/642,712. Claims 1-8, 11-12, 19, 21, 34 and 42-56 are provisionally rejected under obviousness-type double patenting with claims 3, 4, 6-10, 12, 19, 21, 27 and 33-56 of co-pending Application No. 08/642,712.

In response, attorneys for Applicants' respectfully request that these provisional double patenting rejections be held in abeyance until important issues with respect to the subject matter of any of the claims of this application and their co-pending Application No. 08/642,712 can be addressed with respect to the Sasaki patents noted in the Notice under Section 607 on pages 6-7 in the previously submitted Amendment filed under 37 CFR § 1.114 on December 23, 2002 in connection with this application and the Notice under Section 607 in the Response under 37 CFR § 1.111, on pages 6-7 filed on December 23, 2002 in connection with co-pending Application No. 08/642,712. These Notices are reiterated herein, if necessary. Once such issues have been resolved, Applicants will amend the claims in the two applications to avoid the double patenting issues and/or provide an appropriate terminal disclaimer.

Section 112 Rejections

Claims 1, 2, 6-8, 11-12, 19, 21, 42-47 and 52-56 are rejected under Section 112, first paragraph as containing subject matter not sufficiently described in the specification. In particular, the Office Action alleges that the specification provides support for proteins having the claimed molecular weight wherein the assessment of molecular weight is made by means of SDS-polyacrylamide gel electrophoresis (SDS - PAGE) using specifically recited molecular weight standards.

With respect to claims 1, 2, 6-8, 11-12, 19, 21, 42-47 and 52-56, it is respectfully submitted that this rejection is plainly in error and cannot stand. Claim 1, as originally filed and as presently pending, (and claims 2-8, 11-12, 19, 21, 42-47 and 52-56 dependant thereon), clearly recites that the OMP106 polypeptide "has a molecular weight of about 180 kD to about 230 kD as determined in SDS polyacrylamide gel electrophoresis using rabbit skeletal muscle myosin and *E. coli* β-galactosidase as the 200 kD and 116.25 kD molecular weight standards." Thus, these claims are fully consistent with the teaching of the specification as admitted in the Office Action. Hence, this rejection must be withdrawn.

Claims 19, 42-43, 46-49 and 55 and 56 are rejected under Section 112, first paragraph as allegedly non-enabled for a vaccine. The Office Action refers to Dorland's Medical Dictionary 29th Edition, 2000, for a definition of "vaccine" and; "a suspension of attenuated or killed microorganisms (bacteria, viruses, or rickettsiae), or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases." The Office Action asserts that it is "unclear from the specification exactly how the vaccine was produced or used" and what type of immune response was elicited.

Applicants emphatically traverse and submit that this rejection is plainly in error! Attention is directed to the teaching of the specification at Section 5.6 entitled "Vaccines" at

page 28, line 35 through page 31, line 11. As clearly taught therein the vaccines of the present invention comprise an OMP106 immunogen, as described in Section 5.5 at page 24, lines 5 through page 27, line 35, a pharmaceutically acceptable carrier and optionally an adjuvant and other materials found in a vaccine. See, in particular, e.g.; page 29, lines 3-14. As clearly taught at page 29, lines 32-35; "useful polypeptide immunogens include the isolated OMP106 polypeptide and OMP106-derived polypeptides. Preferred immunogens include the purified OMP106 polypeptide and derived polypeptides or peptides of OMP106." Attention is further directed to the teaching of the specification at page 29, line 37 through page 31, line 11. As clearly taught therein, the amount of the immunogen is between 0.1 and 500 mg per dose and as explained at page 29, lines 23-31, is an amount "sufficient to induce an immune response which can prevent *M. catarrhalis* infection or attenuate the severity of any preexisting or subsequent *M. catarrhalis* infections." Suitable pharmaceutically acceptable carriers are described as are suitable adjuvants and suitable routes of administration. As further clearly taught at page 30, lines 23-32, the vaccines are prepared according to teachings known to those skilled in the art given the teachings of the specification.

Finally attention is directed to the Example Section of the specification, in particular, Section 7. Example: Efficacy of OMP106 Vaccine: Cytoxic Activity of Anti-OMP 106 AntiSera at pages 55-56 as well as the methods taught at Section 6.1.8 at pages 46-47. As demonstrated therein, complement-mediated cytoxic activity of polyclonal anti-OMP106 antibodies was examined to determine the vaccine potential of the isolated OMP106 polypeptide. As shown in Table 3 at page 55 and as stated at page 56, lines 1-4, the polyclonal antibodies elicited by administration of isolated OMP106 polypeptide have 8 fold greater cytoxic activity than did pre-immune serum. As concluded at page 56, lines 3-4: "This finding indicates that the isolated OMP106 polypeptide is useful as a vaccine against *M. catarrhalis*." Given the specific teaching of the specification and the exemplary experimental results, it is submitted that one skilled in the art would be able to prepare and use the presently claimed vaccine compositions without undue experimentation. Accordingly, this rejection under Section 112 cannot stand and must be withdrawn.

Claims 1-8, 11-12, 19, 21, 34 and 42-56 are rejected under Section 112, second paragraph as allegedly indefinite. In particular, the term "substantially" as used in claims 1 and 34 is alleged to be indefinite.

Attorneys for Applicants respectfully do **not** agree. Firstly, terms in a claim cannot be read in a vacuum. They must be interpreted in light of the understanding of those skilled in the art given the teaching of the specification. Attention is directed to the teaching of the

specification at page 20, lines 31-37. As clearly taught therein the "term 'purified'" means that the product is substantially free of other biological material with which it is naturally associated. That is comprising a purified OMP106 polypeptide composition is at least 95% pure OMP106 polypeptide by weight, preferable at lest 98% pure OMP106 polypeptide by weight, and most preferred 99% pure OMP106 polypeptide by weight." Hence, those skilled in the art would surely understand what "substantially" pure means in the present claims.

Notwithstanding that Applicants do **not** agree, and in fact traverse this rejection and the grounds on which it is based, merely in order to advance prosecution and obtain coverage for certain embodiments, claim 34 is amended to avoid the term "substantially purified". The claim is directed to isolated OMP106 which is fully supported by the specification and claims as originally filed.

Claims 3 and 4 are rejected as allegedly indefinite with respect to the use of the trademark "ATCC".

As detailed above with respect to the objection to the specification, in light of Exhibit 1, enclosed herewith, it is submitted that, as used in the specification and claims, the phrase "ATCC" is an art recognized abbreviation of the American Type Culture Collection and is not employed as a trademark either by the ATCC or by the Applicants.

Hence, this rejection must withdrawn.

Section 102 Rejection

Claims 1-6, 19, 21, 34, 42, 44, 46, 48, 49, 51 and 53-56 are rejected under Section 102(e) as anticipated by U.S. Patent No. 6,335,018 issued to Sasaki et al., January 2, 2002 (Sasaki I), or U.S. Patent No. 6,440,425, issued to Sasaki et al., August 27, 2002 (Sasaki II), or U.S. Patent No. 6,440,424, issued to Sasaki et al. August 27, 2002 (Sasaki III). Sasaki I is alleged to have priority to May 1, 1995, Sasaki II is alleged to have priority to May 1, 1995 with respect to Sasaki's SEQ ID Nos.: 1 and 2 and Sasaki II is alleged to have priority to May 1, 1995. Each of the three Sasaki patents are alleged to teach "an isolated and purified outer membrane polypeptide of *Moraxella catarrhalis* "having a molecular mass of about 200 kDa as determined by sodium dodecyl sulfate polyacrylamide gel electrophoreisis... an immunogenic composition comprising the polypeptide."

Applicants gratefully acknowledge that this rejection is not raised against claims 7-8, 11, 12, 43, 45, 47 and 52 of the present application.

With respect to the rejected claims, Applicants emphatically disagree and direct attention to a Declaration under 37 CFR § 1.131 (with attached evidence in Exhibits A1, A2 and B-F) i.e., Declaration of Tucker and Plosila. The Declaration and the attached evidence demonstrate their conception and/or reduction to practice, prior to May 1, 1995, of an isolated

outer membrane polypeptide from *Moraxella catarrhalis* of approximately 200 kDa as determined by SDS-PAGE, fragments of same, use as a vaccine and a method of inducing an immune response to the isolated OMP106 polypeptide or peptide.

With respect to the isolation and purification of OMP106 from *Moraxella catarrhalis,* attention is directed to Exhibits B, C and F and paragraphs 6-7 and 10 of the Tucker and Plosila Declaration. Such evidence clearly demonstrates present Applicants' conception and reduction to practice of isolated and purified OMP106 prior to April 1, 1995.

With respect to immunogenic compositions, vaccine compositions and methods of inducing an immune response using the isolated OMP106 (or fragments containing epitope thereof), attention is directed to the evidence; in particular, Exhibits D and E and paragraphs 8, 9 and 11 of the Tucker and Plosila Declaration. Such evidence clearly demonstrates Applicants' conception and completion of the invention which encompasses vaccines and a method of producing an immune response to said OMP106 polypeptide and fragments before April 1, 1995. Attention is directed especially to paragraph 11 of the Tucker and Plosila Declaration. As explained therein and shown in Exhibit D, prior to April 1, 1995, the present Applicants had forwarded to Dr. Noel of HRP, Inc. an immunogenic composition comprising isolated OMP106 of *M.catarrhalis* with an immunization schedule for use to induce an immune response in an animal model, i.e. NZW rabbit. As further explained in paragraph 11 of the Tucker and Plosila Declaration, and demonstrated in Exhibit E prior to April 1, 1995 Applicants had obtained evidence that their isolated OMP106 preparation was useful as an immunogenic preparation to induce an immune response against *M.catarrhalis*. This evidence also demonstrates Applicants' invention of vaccine compositions as well.

It is respectfully submitted, that the evidence presented in the Declaration of Tucker and Plosila clearly demonstrates Applicants' conception and/or reduction to practice of all the presently claimed subject matter prior to the earliest priority date of any of the Sasaki patents. Hence, the rejection based on these patents cannot stand and must be withdrawn.

Respectfully submitted,

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